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DEPARTMENT OF ENERGY

National Nuclear Security Administration

Exports of U.S.-Origin Highly Enriched Uranium (HEU) for Medical Isotope Production: Certification of Sufficient Supplies of Non-HEU-based Molybdenum-99 (Mo-99) to Meet Needs of Patients in the United States

AGENCY: National Nuclear Security Administration (NNSA), Department of Energy (DOE).

ACTION: Notice.

SUMMARY: DOE and Department of Health and Human Services (HHS), in accordance with the American Medical Isotopes Production Act of 2012 (AMIPA), have issued a joint Secretarial certification that there is a sufficient global supply of Mo-99 produced without the use of HEU available to meet the needs of patients in the United States and that it is not necessary to export United States-origin HEU for the purposes of medical isotope production in order to meet United States patient needs. This certification is effective as of January 2, 2022.

FOR FURTHER INFORMATION CONTACT: Requests for additional information may be sent to Max Postman in the Office of Conversion *OfficeofConversion@nnsa.doe.gov* or 202-586-9114

SUPPLEMENTARY INFORMATION:

Authority and Background:

The American Medical Isotopes Production Act of 2012 (AMIPA) (subtitle F, Title XXXI of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-139)), enacted on January 2, 2013, amended section 134 of the Atomic Energy Act of

1954 (42 U.S.C. 2160d) by striking subsection c. and inserting language that prohibits the Nuclear Regulatory Commission (NRC) from issuing a license for the export of HEU from the United States for the purposes of medical isotope production, effective seven years after enactment of AMIPA, subject to a certification regarding the sufficiency of Mo-99 supply in the United States.

AMIPA requires the Secretary of Energy to either jointly certify, with the Secretary of Health and Human Services, that there is a sufficient supply of Mo-99 produced without the use of HEU available to meet U.S. patient needs, and that it is not necessary to export U.S.-origin HEU for the purposes of medical isotope production in order to meet U.S. patient needs, or to unilaterally certify that there is insufficient supply of Mo-99 produced without the use of HEU available to satisfy the domestic market and that the export of U.S.-origin HEU for the purposes of medical isotope production is the most effective temporary means to increase the supply of Mo-99 to the domestic U.S. market, thereby delaying the enactment of the export license ban for up to six years.

DOE published a *Federal Register* notice (85 FR 3362) on January 21, 2020 certifying that, at the time, there was an insufficient global supply of Mo-99 produced without the use of HEU and that the export of U.S.-origin HEU for the purposes of medical isotope production was the most effective temporary means to increase the supply of Mo-99 to the domestic U.S. market. This certification was effective for no more than two years from the effective date of January 2, 2020. The *Federal Register* notice stated that DOE would conduct periodic reviews of the domestic U.S. and global Mo-99 market and would work toward a certification to Congress, regarding the sufficiency of supply as soon as the statutory conditions are satisfied.

Based on an expert third party market analysis, as well as the assessment of subject matter experts in both agencies, the Secretary of Energy and the Secretary of

Health and Human Services have jointly certified that there is a sufficient global supply of Mo-99 produced without the use of HEU available to meet the needs of patients in the United States. Furthermore, while there is the potential for future shortages of other medical isotopes, including iodine-131 and xenon-133, the export of HEU would not mitigate these risks. Therefore, the Secretaries also have jointly certified that it is not necessary to export United States-origin HEU for the purposes of medical isotope production in order to meet United States patient needs.

This joint certification reflects DOE's progress in working with international partners to convert medical isotope production facilities to the use of low enriched uranium (LEU) and in supporting the establishment of domestic supplies of Mo-99 produced without use of HEU. Three of the four major global producers now produce Mo-99 using LEU. The other major producer still relies partially on HEU but is on track to convert to LEU-based processes in 2022. The Department of Health and Human Services has also played a critical role in achieving this milestone, including approval of LEU Mo-99 technologies and through the 2018 approval of a New Drug Application for the first domestic production of Mo-99 in nearly 30 years.

The global market is now capable of producing enough Mo-99 using LEU to meet U.S. demand, but ongoing engagement between producers, radiopharmaceutical companies, and other private sector stakeholders will be needed to ensure that U.S. patient needs continue to be met. Mo-99 producers must continue to coordinate regarding the security of global supply and must maintain the ability to ramp up production where needed to compensate for shortfalls from other producers and maintain accessibility of Mo-99 through the supply chain. DOE will reinforce this message through its ongoing engagements with the Mo-99 community.

Signing Authority

This document of the Department of Energy was signed on December 8, 2021, by Corey Hinderstein, Deputy Administrator for Defense Nuclear Nonproliferation, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the *Federal Register*.

Signed in Washington, DC, on December 21, 2021.

Treena V. Garrett,
Federal Register Liaison Officer,
U.S. Department of Energy.

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